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Patent

Remarks

The invention relates to devices for conducting assays, including qualitative, semi-quantitative and quantitative determinations of a plurality of analytes in a single test format. Claims 74-113 are pending in the application. The Examiner has indicated that claims 101-113 are in allowable form.

Claims 74, 77, and 79-88 have been rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly obvious over claims 1-21, 1-44, 1-50 and 1-15 of U.S. Patents 6,143,576; 6,156,270; 6,019,944; and 5,458,852, respectively. Claims 74, 77-84, 86, 88, 89, 91-93, 95, and 97-100 have been rejected under 35 U.S.C. §102(e), as allegedly being anticipated by Sun *et al.*, U.S. Patent 5,238,652 ("the '652 patent"). Claims 78, 85, 87, and 94 have been rejected under 35 U.S.C. §103(a), as allegedly being obvious in view of the '652 patent. The Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Art-Based Remarks

Obviousness-type double patenting

Applicant acknowledges the rejection of claims 74, 77, and 79-88 as allegedly being unpatentable over U.S. Patents 6,143,576; 6,156,270; 6,019,944; and 5,458,852. A terminal disclaimer is being submitted herewith.

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 74, 77-84, 86, 88, 89, 91-93, 95, and 97-100 under 35 U.S.C. §102(e), as allegedly being anticipated by Sun *et al.*, U.S. Patent 5,238,652 ("the '652 patent").

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*, MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of

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anticipation. Only when a *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. See, e.g., *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The devices of the instant claims require, *inter alia*, the following elements (see, e.g., claim 74):

1. a diagnostic element comprising a capillary space through which a sample flows,
2. a non-absorbent surface within the capillary space, and
3. a plurality of discrete capture zones on the nonabsorbent surface, each discrete capture zone comprising a capture element that binds one of a plurality of different target ligands.

As Applicant discussed in the previous office action response, the '652 patent does not disclose any devices having a nonabsorbent surface within a capillary space that comprises a plurality of discrete capture zones. Instead, the devices of the '652 patent use a "porous chromatographic membrane support... impregnated with a specific antigen or probe" as a means for binding analytes for detection. See, e.g., '652 patent, column 4, lines 57-62; column 5, lines 1-6; and column 5, lines 21-37. Indeed, the instant invention is designed specifically to overcome problems inherent in precisely this prior art type of membrane-containing device. See, e.g., specification, page 5, lines 3-19. Applicant, therefore, respectfully submits that the '652 patent fails to disclose each and every element of the instant claims.

The Examiner's rejection appears to be flawed. According to the Examiner, the housing (201) of the '652 patent reads on Applicant's non-absorbant surface because the housing is "in contact with the capillary and capture zones." Paper 21, page 4. This statement is at scientific odds with the '652 patent itself which clearly distinguishes the housing from the porous chromatographic support, the latter and not the former of which includes the specific antigen or probe. According to the '652 patent, the chromatographic membrane support is "disposed within the test kit housing." '652 patent, col. 4, lines 57-58. Thus, the housing is distinct from the porous membrane. Furthermore, the probes of the '652 patent are located on the porous

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chromatographic membrane, not the support. Applicant respectfully submits that probes on a porous membrane would not be considered by the skilled artisan to be equivalent to a plurality of discrete capture zones on a nonabsorbent surface. Furthermore, to interpret capture probes on a porous membrane as being equivalent to discrete capture zones on a nonabsorbent surface is not scientifically correct, and in conflict with the teachings of the '652 patent.

Furthermore, it is noted that the Examiner has provided no legal basis for the alleged proposition that different things which are "in contact" "read" on each other. Applicant requests that the Examiner cite to any such legal precedent supporting this notion.

Furthermore, the Examiner apparent rebuttal that the instant claim language is open and does not exclude additional porous zones" (paper no. 21, 4) is entirely misplaced. It is not Applicant's position that the '652 patent teaches porous zones. Applicant's position is that the '652 patent does not teach a non-absorbant surface with a plurality of discrete capture zones on that surface. Nowhere does the '652 patent describe to attach the probe to the housing. The '652 patent only describes to attach the probe to the porous membrane, which is contained within the housing. Because the porous membrane and the housing are structurally and functionally distinct, the Examiner's attempt to make them equivalent is flawed.

Moreover, the instant claims recite that the "discrete capture zones" comprise "a capture element that binds one of a plurality of different target ligands." In contrast, the device of the '652 patent is designed to operate in a completely different fashion. As described in column 4, lines 47-62, the porous chromatographic membrane comprises probes that compete with the antigen for binding to an antibody on latex particles. In the '652 patent, probe bound to the porous membrane does not react with the target ligand but is itself the target ligand. Thus, in the '652 patent, the only surfaces in the device comprising a capture element that binds to a target ligand are the surfaces of the latex spheres; and nowhere in the '652 patent do such latex spheres provide a plurality of discrete zones on a nonabsorbent surface, each binding to one of a plurality of different target ligands as required by the instant claims.

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Therefore, because the '652 patent fails to provide each and every element set forth in the claims, no *prima facie* case of anticipation has been established. Applicant respectfully requests that the rejection under 35 U.S.C. §102 be reconsidered and withdrawn.

35 U.S.C. § 103

Applicant respectfully traverses the rejection of claims 78, 85, 87, and 94 under 35 U.S.C. §103(a), as allegedly being obvious in view of Sun *et al.*, the '652 patent.

To establish a *prima facie* case of obviousness, three criteria must be met; there must be some motivation or suggestion, either in the cited publications or in knowledge available to one skilled in the art, to modify or combine the cited publications; there must be a reasonable expectation of success in combining the publications to achieve the claimed invention; and the publications must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2142. In analyzing obviousness, the Court of Appeals for the Federal Circuit has repeatedly cautioned that:

[t]he factual inquiry... must be based upon objective evidence of record.... [T]he best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.... [P]articular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

In re Sang-Su Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (internal citations omitted).

As discussed above, because the '652 patent does not provide each and every element set forth in the independent claims, any *prima facie* case of obviousness must also provide the missing elements and some motivation for the skilled artisan to undertake suitable modification of the '652 devices in order to arrive at the instantly claimed invention. Since the teachings of the '652 patent are not properly considered in the anticipation rejection, the obviousness rejection

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has not considered the need to identify the missing elements and to establish such a motivation. Applicant respectfully submits that, for this reason, no prima facie case of obviousness has been established.

Additionally, with regard to dependent claims 78, 85, 87, and 94, the Examiner asserts without reference to any objective evidence of record that "[t]he selection of a covalent binding, the size range of the particle and the use of a fluorescent label are all result effective variables," and that therefore optimization of these variables is within the skill of the art. Paper No. 18, page 5. However, the recognition that a particular parameter is a result-effective variable must come from the prior art, and not from an unsupported assertion of the Examiner. *See, e.g.*, MPEP § 2144.05(II)(B). In contrast, nothing of record discloses the use of a time gate (claim 78), immobilization of nanoparticles to a nonabsorbent surface through adsorption or covalent bonds (claim 85), immobilization of particles having a diameter of 0.1mm to 10 mm to a surface through covalent bonds (claim 87), or generating a plurality of detectable signals using fluorescent labels (claim 94).

Applicant has requested that the Examiner provide objective evidence that such elements are result-effective variables, and of the various alleged "advantages" asserted by the Examiner, so that Applicant might have a fair opportunity for response to the rejection. The Examiner responds only that "the court has decided that these matters are within the skill of the art and are not ordinarily a matter of invention." Paper No. 21, page 4. Applicant reiterates the previous request for some objective evidence in support of the Examiner's allegations, and further requests some evidence in support of what the Examiner believes is considered "ordinarily a matter of invention" in the immunoassay arts.

The Examiner's response to Applicant's remarks highlights the reasons why courts have insisted on a rigorous application of the requirements to establish a *prima facie* case of obviousness, a standard that the present rejection fails to meet. For example, as Applicant pointed out, instant claim 85 refers to immobilization of nanoparticles to a nonabsorbent surface

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through adsorption or covalent bonds. In contrast, the Examiner continues to refer to the covalent binding of immunogens to a particle, which is irrelevant to this claim. See, e.g., Paper No. 21, page 5 ("The bond referenced to by the office is that between the binding material and the latex particle"). The assertion that it would have been obvious to select covalent bonds for the advantage of "being very strong" (Paper No. 18, page 5) remains unsupported by any evidence of record. Moreover, as Applicant has pointed out, immobilization of the latex particles to a nonabsorbent surface would render the devices disclosed in the '652 patent unsuitable for their intended use, as in the '652 devices, particles must be free to flow through the devices (see, e.g., '652 patent, column 6, lines 49-58), and immobilization to a surface by covalent bonds would prevent such flow. A modification that renders the prior art unsatisfactory for its intended purpose cannot support a *prima facie* case of obviousness. MPEP § 2143.01.

Because the cited '652 patent, even if modified as suggested by the Examiner, fails to teach or suggest the instantly claimed devices, and because no motivation has been established for the modifications proposed by the Examiner, Applicant respectfully submits that no *prima facie* case of obviousness has been established. Applicant therefore requests that the rejection under 35 U.S.C. §103 be reconsidered and withdrawn.

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CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

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